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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services,

Defendant.

No. 2:21-CV-00326-TOR

DEFENDANT'S REPLY IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

The claims at issue were paid. Plaintiff received the coverage to which he was entitled, and has not been harmed in any way. The case should be dismissed for lack of jurisdiction.

Alternatively, to the extent jurisdiction has been established, the Court should enter judgment in Plaintiff's favor on Count II, remand with instructions to vacate the post-payment administrative "denials," and enter judgment for Defendant on all other claims.

II. REPLY ARGUMENT

A. Plaintiff's speculation that the Secretary might pursue recoupment in the future does not establish Article III jurisdiction.

Plaintiff does not deny that the April 2019 and March 2021 claims were paid long before the administrative decisions from which he appeals to this Court. Nor does Plaintiff deny that, as of the date of this filing, he has not been harmed by those decisions.

Plaintiff bears the burden of establishing Article III jurisdiction. *Spokeo, Inc. v. Robbins*, 578 U.S. 330, 338 (2016). He must show a concrete and particularized injury that is "actual or imminent, not conjectural or hypothetical." *Id.* at 339 (citation omitted). All Plaintiff has offered is a hypothetical assertion that he might be harmed in the future if the Secretary attempts to recoup the payments. ECF No. ECF No. 67 at 5 (citing AR 12, 390). That assertion fails for a host of reasons.

First, the Secretary paid the claims in accordance with the *Olsen I* judgment, which held that Plaintiff was entitled to have his CGM device and associated supplies covered by Medicare. ECF No. 65 at 3-4. That judgment is *res judicata* on the issue of coverage. The Secretary recognized that when he paid the claims, and he continues to recognize that now. The Secretary has no plans to attempt recoupment in defiance of the *Olsen I* judgment.

Second, independently of the *Olsen I* judgment, the Secretary is bound by, and continues to apply, the new policy set forth in the DME Final Rule, which provides

that CGMs and their supplies are covered by Medicare as durable medical equipment, where medically indicated. ECF No. 65 at 7-10. The Secretary would lack a basis for pursuing recoupment of the claims at issue because the former CMS Ruling pursuant to which the claims were nominally "denied," CMS 1682-R, has been rescinded and replaced with (1) DME Final Rule, which extends coverage to virtually all CGM devices; and (2) a new CMS Ruling, CMS 1738-R, which formally rescinds CMS 1682-R and applies the substantive terms of the DME Final Rule even retroactively to properly-pending and future claims and appeals. ECF No. 65 at 7-10. Given that CMS 1682-R has been rescinded and replaced, it is not clear how the Secretary could recoup the payments pursuant to that ruling (which the Secretary has no intention of doing anyway). Because the Secretary has no straightforward path to recouping the payments, any possibility of future harm is purely speculative and thus not sufficient to establish jurisdiction.

Third, the record does not support Plaintiff's claim that recoupment is on the horizon. Plaintiff suggests that the Secretary has "conceded" this issue. ECF No. 67 at 7. But the citations he offers are not persuasive. AR 12 is the final page of the Medicare Appeals Council's post-payment "denial" of the April 2019 claim. The cited language is a boilerplate sentence which states (consistent with the "denial" of coverage), that Plaintiff "remains financially responsible for the non-covered costs." AR 12. AR 390 is the final page of the ALJ's "denial" of the March 2021 claim. Here again, the cited language is a boilerplate recitation that Plaintiff "is financially

responsible for the non-covered costs." AR 390. These two sentences do not give rise to an Article III case or controversy. Read in context, they are mere summaries of the "denials" of coverage. They are not admissions that the Secretary might attempt to recoup the payments in the future.

Finally, assuming *arguendo* that Plaintiff could establish an actual or imminent threat of recoupment, the remedy is to do what the Secretary has offered to do from day one: remand the case with instructions to vacate the administrative "denials." *See* ECF No. 65 at 21. As previously explained, the proper procedure for doing so is to enter judgment in Plaintiff's favor on Count II, and to enter judgment in the Secretary's favor on all remaining claims. *Id.*

B. The Court should adopt the mootness analysis in *Smith v. Becerra*.

Plaintiff urges the Court to ignore the Tenth Circuit's decision in *Smith v. Becerra*, 44 F.4th 1238 (10th Cir. 2022), arguing that the case was wrongly decided. *See* ECF No. 67 at 15-16 ("[T]he Tenth Circuit simply assumed that the Secretary would not engage in continued wrongful behavior by denying CGM claims.").

The Court should decline that invitation. The mootness analysis in *Smith* is persuasive and directly on point. Contrary to Plaintiff's assertions, the Tenth Circuit did not "simply assume" the Secretary would not continue apply CMS 1682-R in the future. The Court thoroughly scrutinized the Secretary's adoption of the DME Final Rule, the Technical Direction Letter, and CMS 1738-R—including the timing issues Plaintiff raises here—and concluded that there was no reasonable probability that the

Secretary would continue denying claims under CMS 1682-R. *Id.* at 1251-52. As the Court pointedly noted, the Secretary has spent "the past several years" implementing a "wholesale change in policy" regarding CGM coverage. *Id.* at 1251. Unwinding the new policy would require the Secretary to disavow his current support for broad CGM coverage by embarking on a new round of notice-and-comment rulemaking. *Id.* That is highly unlikely to occur. *Id.*

Plaintiff also makes a passing suggestion that the Tenth Circuit might revisit *Smith* because the Secretary denied one of the plaintiff's CGM claims after the case was decided. *See* ECF No. 67 at 16 ("[A]mazingly, the Secretary actually denied another of Smith's claims within days of the Tenth Circuit's decision and the Tenth Circuit has called for a response by the Secretary due October 25.").

This suggestion is meritless. It is true that the Secretary denied one of Ms. Smith's CGM claims after the Tenth Circuit issued its decision. But, contrary to Plaintiff's suggestion, the denial was not based on CMS 1682-R. As the Secretary explained in a declaration filed in support of his opposition to Ms. Smith's petition for rehearing or rehearing en banc (attached hereto as **Appendix A**), the claim in question was denied because Ms. Smith's supplier, MiniMed, submitted the claim to CMS with an incorrect billing code. Appendix A at ¶¶ 4, 10, 14. MiniMed has acknowledged that mistake, and has reportedly chosen to write off the amount of the claim, with no financial impact to Ms. Smith. *Id.* at ¶ 13. Because the denial in question had nothing to do with the issues it addressed, the Tenth Circuit is unlikely to revisit its decision.

C. Plaintiff should not be permitted to manufacture jurisdiction through his own vexatious conduct.

Defendant suggested in his opening brief that Plaintiff misled the ALJ and the Medicare Appeals Council by (1) concealing the fact that the claims had already been paid; and (2) not disclosing the existence of the *Olsen I* judgment. ECF No. 65 at 6, 13-14.

Plaintiff did not respond to this argument. His silence is telling. If there was an innocent explanation for Plaintiff not presenting the full picture to the tribunals below, he presumably would have offered it here.

The truth is this: Plaintiff *wanted* the claims to be denied so that he could run back to this Court (Judge Mendoza) and accuse the Secretary of defying the *Olsen I* judgment. Why? Because he hoped it would prompt the Court to issue a nationwide injunction that was eluding his counsel in other cases. Plaintiff's complaint and early preliminary injunction filings confirm that was his plan. *See, e.g.*, ECF No. 1 at ¶¶ 2-6 (complaint accusing Secretary of defying *Olsen I* judgment and engaging in more "bad faith" conduct); ECF No. 6 at 1 ("Even after this Court's 'bad faith' finding, the Secretary continued to reject CGM claims, including claims by Mr. Olsen, on the 'bad faith' grounds."); ECF No. 22 at 1-2 ("It is precisely the Secretary's failure to understand the 'bad faith' nature of his conduct that has led to a second suit in this Court by Mr. Olsen within one year. . . . The fact that the Secretary continued and continues to engage in the bad faith conduct after this Court's ruling, indicates that

stronger measures are necessary.").

Jurisdiction cannot be manufactured through a contrived controversy. Had Plaintiff been candid with the tribunals below, the post-payment "denials" would never have been issued, and this case would never have been filed. The Court should dismiss the case for lack of a bona fide controversy.

D. Plaintiff's remaining contentions are unpersuasive.

1. Filing of Administrative Record

Plaintiff suggests that Defendant engaged in "vexatious conduct" by not filing the Administrative Record at the same time as his answer. ECF No. 67 at 1-2.

This claim is meritless. First, Defendant was not obliged to file the answer and Administrative Record when he did. As explained in a prior filing, Plaintiff failed to exhaust administrative remedies as to the March 2021 claim by not appealing the ALJ's October 26, 2021 decision to the Medicare Appeals Council. ECF No. 21. Defendant could have responded to the complaint by filing a motion to dismiss for lack of jurisdiction, which would have delayed the filing of an answer by at least two months. But Defendant instead elected to file an answer so that the case could move toward an efficient resolution. That was not vexatious conduct.

Second, Plaintiff's failure to appeal the March 2021 claim to the Medicare Appeals Council caused a delay in the preparation of the Administrative Record. Had Plaintiff properly appealed, the record materials for the March 2021 claim would have been compiled at that time. Because Plaintiff did not appeal, however, the materials

remained scattered and unfinalized. Most notably, because Plaintiff had not appealed the ALJ's decision, CMS did not prepare a transcript of the October 8, 2021 hearing before the ALJ. After learning of that problem, Defendant promptly engaged a local court reporter to prepare a transcript on an expedited basis so that the record for the March 2021 claim could be finalized before the hearing on Plaintiff's preliminary injunction motion. Again, this was not vexatious conduct.

Finally, the preparation of the Administrative Record was hindered by Plaintiff's own conduct. As outlined above, Plaintiff concealed the *Olsen I* judgment and the fact that the claims at issue had been paid. That concealment led to weeks of confusion among defense counsel and the CMS employees responsible for preparing the Administrative Record. Plaintiff should not be heard to complain about a delay in the filing of the record when he was partially responsible for the delay.

2. Contents of Administrative Record

Plaintiff contends that the record contains "improper materials" that the Court is forbidden from considering. ECF No. 67 at 3-5 (referencing AR 29-42, AR 510-45, and AR 561-69).

The record in an APA case consists of "everything that was before the agency pertaining to the merits of its decision." *Goffney v. Becerra*, 995 F.3d 737, 747 (9th Cir. 2021). Any document that was "directly or indirectly considered" may be included. *Id.* Evidence that was "excluded by the adjudicator" is also properly included. *Id.* (citing 42 C.F.R. § 405.1042(a)(2)). The agency's compilation of the

administrative record is subject to a presumption of regularity. *Id.* at 748.

The "materials" to which Plaintiff objects are administrative documents that prove his claims were paid in accordance with the *Olsen I* judgment. They pertain directly to the Secretary's decision to pay the claims at issue, and were thus properly included in the record. These documents can also be considered

AR 29-42 is a remittance notice issued by the Secretary's claims processing contractor, Noridian, to Plaintiff's CGM supplier, MiniMed. The remittance notice shows that the April 2019 and March 2021 claims were paid in July 2021, along with 9 other claims that are not at issue in this case. AR 29, 36-37. This same remittance notice also appears at AR 532-44.

AR 510 is an email from CMS to Noridian instructing Noridian to pay (1) the CGM claim that was at issue in *Olsen I*; and (2) "all CGM-related claims for this beneficiary [Plaintiff] going forward." AR 510. Attached to this email were the *Olsen I* complaint (AR 511-27) and *Olsen I* summary judgment order (AR 528-31).

AR 561-69 is email correspondence between CMS and Noridian re-confirming that the April 2019 and March 2021 claims (in addition to the 9 others referenced in the July 2021 remittance notice) had been paid. This correspondence also confirms that another claim with date of service October 13, 2021, which is not at issue in this case, had also been paid.

In objecting to these materials, Plaintiff is asking the Court to decide the case in an alternate universe in which his claims were not paid. The Court should not oblige.

The claims were paid. Plaintiff knows it. The record proves it. Case closed.[1]

3. Death and Injury Allegations

Plaintiff argues throughout his summary judgment briefing that the Secretary caused thousands of deaths and injuries by denying CGM claims under the now-rescinded CMS 1682-R. ECF No. 51 at 1, 2, 7; ECF No. 64 at 4, 9, 10-11, 12; ECF No. 67 at 1, 6, 9, 15.

There is no factual support whatsoever for this claim. Plaintiff's citations to documents filed by his attorney in a companion case in U.S. District Court for the District of Columbia, *Lewis v. Becerra*, 18-CV-2929-RBW, are not persuasive. The cited filings (ECF Nos. 63 and 81) are briefs filed in support of a class certification motion. Neither filing even mentions deaths or injuries caused by denials of claims under CMS 1682-R, much less provides proof that any deaths or injuries occurred.

The truth is that there is no evidence linking the Secretary's prior policy of not covering "non-therapeutic" CGMs to deaths or injuries. And there is certainly no evidence that the Secretary was aware of any purported connection when that prior policy, CMS 1682-R, was adopted in 2017.

[1] Even if the Court concludes that the challenged documents are not "administrative record" materials, it can and should consider them for purposes of deciding whether subject matter jurisdiction has been established. *See, e.g.*, *Colorado Env't Coal. v. Off. of Legacy Mgmt.*, 819 F. Supp. 2d 1193, 1202 (D. Colo. 2011), *amended on reconsideration*, Case No. 08-CV-01624-WJM-MJW, 2012 WL 628547 (D. Colo. Feb. 27, 2012) ("While a court's review of the merits in an APA case is generally limited to the administrative record, a court may consider extra-record materials for purposes of determining whether it has jurisdiction over the matter before it.").

III. CONCLUSION

The claims at issue were paid long before they were nominally "denied." Plaintiff received the coverage to which he was entitled. He has not been harmed in any way, and will not be harmed in the future. The case should be dismissed.

DATED this 31 day of October, 2022.

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CERTIFICATE OF SERVICE

I hereby certify that on October 31, 2022, I caused to be delivered via the method listed below the document to which this Certificate of Service is attached (plus any exhibits and/or attachments) to the following:

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